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VIA ELECTONIC SUBMISSION: <https://www.regulations.gov/document/FDA-2024-N-1718-0001>

May 23, 2024

Endocrinologic and Metabolic Drugs Advisory Committee  
Food and Drug Administration  
Department of Health and Human Services  
Silver Spring, MD 20993-0002

RE: Biologics License Application 761326 for NNC0148-0287 Injection (Insulin Icodec) [Docket No. FDA-2024-N-1718]

The Association of Diabetes Care & Education Specialists (ADCES) appreciates the opportunity to comment on Docket No. FDA-2024-N-1718 regarding the biologics license application for Insulin Icodec.

ADCES is an interdisciplinary professional membership organization dedicated to improving prediabetes, diabetes, and cardiometabolic care through innovative education, management, and support. With more than 12,000 professional members including nurses, dietitians, pharmacists, and others, ADCES has a vast and diverse network of practitioners working to optimize care and reduce complications.

Diabetes care and education specialists (DCESs) working in direct patient care provide collaborative, comprehensive, person-centered care and education to people with diabetes, prediabetes, and cardiometabolic conditions. DCESs work with people with all forms of diabetes on healthy coping, healthy eating, being active, taking medication (including insulin), monitoring, reducing risks, and problem-solving.<sup>1</sup> Through these relationships with patients, DCESs have an intimate understanding of the burden of living with diabetes and maintaining relentless self-management routines required to optimize or sustain life with diabetes.

Basal insulin is just one part of the highly individualized care plan that many people with diabetes are self-managing daily. Of people with type 1 diabetes, nearly 40% are missing at least 1 dose of basal insulin each month.<sup>2</sup> Missing insulin doses can lead to life-threatening short-term complications such as diabetes ketoacidosis and, over time, can lead to myriad long-term complications.

There are also special considerations for the older adult population for whom self-management can eventually become impaired due to cognitive or physical declines. Caregivers of older adults with diabetes also face challenges in attempting to manage such a complex condition.

Innovations such as once-weekly basal insulin that reduce the frequency with which medications need to be administered are one step towards reducing the burden of self-management of diabetes and therefore reducing the short-term and long-term clinical impacts from missed doses.

If determined by the Committee and the FDA to be safe and effective, having access to a once-weekly basal insulin can help to improve care, health outcomes, and quality of life for individuals with diabetes who use basal insulin as part of their care plan.

ADCES appreciates the opportunity to comment on this biologics license application. Please contact ADCES director of advocacy Hannah Martin at [hmartin@adces.org](mailto:hmartin@adces.org) should you have any questions regarding ADCES' comments.

Sincerely,

A handwritten signature in black ink that reads "Hannah E Martin". The signature is written in a cursive style with a clear, legible font.

Hannah Martin, MPH, RDN  
Director of Advocacy  
Association of Diabetes Care & Education Specialists

## References

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<sup>1</sup> ADCES7 Self-Care Behaviors. <https://www.adces.org/diabetes-education-dsmes/adces7-self-care-behaviors>

<sup>2</sup> Smythe et al. Carbohydrate knowledge, lifestyle and insulin: an observational study of their association with glycaemic control in adults with type 1 diabetes. *J Hum Nutr Diet.* 2018 Oct;31(5):597-602. doi: 10.1111/jhn.12561.